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09/916,394	07/26/2001	Marc Gianotti	JM-009 CIP2	7774

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EXAMINER
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THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

18

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/916,394

Applicant(s)

GIANOTTI ET AL.

Examiner

Michael Thaler

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-27 and 61-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-27 and 61-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Art Unit: 3731

Applicant is advised that should claim 3 be found allowable, claim 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 61-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 61 indicates that a single stent is being claimed. However, the body of the claim refers to a plurality of tubular members having longitudinal axes with different degrees of curvature, contradicting the preamble and making it unclear if only a single stent or a plurality of stents is claimed. In claim 62, the structure has already been claimed in claim 61 as a tubular member, resulting in a double recitation of the same element.

Claims 1-3, 5-7, 9, 10, 15, 16, 20-27, 61-68, 73, 74 and 78-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611). Caro discloses a stent comprising a tubular member having a

Art Unit: 3731

curved longitudinal axis wherein the degree of curvature of the stent substantially matches the curvature of the body lumen that it is implanted in (page 3, lines 5-20 and page 10, lines 1-30). Caro fails to specifically indicate that the curvature of the longitudinal axis is obtained by mapping the curvature of the body lumen. However, the patentability of a product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process (M.P.E.P. 2113). In this situation, the product (i.e., the stent which has a degree of curvature of the stent that substantially matches the curvature of the body lumen, wherein the degree of curvature of the longitudinal axis of the stent is obtained by mapping the curvature of the body lumen) in the product by process claim is certainly the same as or obvious from the product (i.e., the stent which has a degree of curvature of the stent that substantially matches the curvature of the body lumen) of Caro. The Caro specification fails to specifically indicate that the stent is adapted for expansion from a collapsed delivery configuration to an expanded deployed configuration. However, it was well known that stents are typically deployed in this fashion. For example, Van Oepen

Art Unit: 3731

teaches that a stent should be adapted for expansion from a collapsed delivery configuration to an expanded deployed configuration (abstract) apparently so that it can be transported through a blood vessel, while collapsed, without harming it. It would have been obvious to make the Caro stent adapted for expansion from a collapsed delivery configuration to an expanded deployed configuration so that it too would have this advantage. As to claim 2, Van Oepen teaches that the stent may be self-expandable (noting col. 2, lines 16-21 of U.S. Patent 6,602,285 which is merely cited for its English language of the disclosure of WO 00/32241). As to claims 20-25, Caro fails to disclose the specific web structure of the stent. However, Van Oepen teaches that a stent should be so constructed so that it provides a very stable construction in the expanded state (col. 1, lines 36-56 of U.S. Patent 6,602,285). It would have been obvious to so construct the Caro stent so that it too would have this advantage. As to claims 26 and 27, Caro fails to disclose a balloon catheter to deploy the stent. However, Van Oepen teaches that a balloon catheter may be used to deploy a stent (col. 2, lines 16-21 of U.S. Patent 6,602,285) apparently so that the degree of expansion may be accurately controlled by the practitioner. It would have been obvious to use a balloon catheter to deploy the Caro stent so that it too

Art Unit: 3731

would have this advantage. Claim 61, as best understood, defines a single stent comprising a tubular member having a predetermined degree of curvature that closely matches the curvature of the body lumen. The method of obtaining this stent, i.e. by producing a plurality of stents with different curvatures and selecting the stent that most closely matches the curvature of the body lumen is a process in the product by process limitation. In this situation, the final product (i.e., a single stent which has a degree of curvature of the stent that closely matches the curvature of the body lumen) in the product by process claim is certainly the same as or obvious from the product (i.e., the stent which has a degree of curvature of the stent that closely matches the curvature of the body lumen) of Caro.

Claims 11-14 and 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611) as applied to claims 1 and 61 above, and further in view of Lukic et al. (5,709,703). Caro fails to disclose a delivery catheter having an inner and outer sheath to deploy the stent. However, Lukic et al. teach that a delivery catheter having an inner and outer sheath may be used to deploy a stent (col. 6, lines 31-60) apparently so that it can be easily deployed. It would have been obvious to use such a

Art Unit: 3731

catheter to deploy the Caro stent so that it too would have this advantage. As to claim 14, Lukic et al. fails to disclose an imaging transducer on the delivery catheter. However, it was well known to include such an imaging transducer on an intravascular catheter so that it could provide an image of the interior of the blood vessel. It would have been obvious to include an imaging transducer on the Lukic et al. delivery catheter so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03).

Claim 17 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611) as applied to claims 1 and 61 above, and further in view of Kula (EP 1042997). Caro fails to disclose the thickness of the stent changing along the longitudinal axis of the stent. However, Kula teaches that a stent should be so constructed in order to protect the artery or to provide increased radiopacity at the ends of the stent (col. 6, lines 6-10 and col. 9, lines 17-25). It would have been obvious to so construct the Caro stent so that it too would have this advantage.

Art Unit: 3731

Claims 18, 19, 76 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611) as applied to claims 1 and 61 above, and further in view of Kitakoa et al. (6,174,326). Caro fails to disclose a coating on the stent. However, Kitakoa et al. teach that a coating should be on a stent in order to retard thrombus formation (abstract). It would have been obvious to provide a coating on the Caro stent so that it too would have this advantage.

Applicant's arguments filed Feb. 10, 2004 have been fully considered but they are not persuasive for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



Art Unit: 3731

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
2/27/04



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731